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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/738,847	Applicant(s) DENG ET AL.	
	Examiner J. Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-48,50-61,65,66 and 70-73* is/are pending in the application.

4a) Of the above claim(s) *45-48,50,65,66 and 70-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-44 and 51-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Claims 36-48, 50-61, 65, 66 and 70-73 are pending in the application.

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 36-44 and 51-61) in Paper No. 7 is acknowledged.

2. Claims 45-48, 50, 65, 66 and 70-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Elected claims 36-44 and 51-61 are examined herein.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112, Second Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 36-44, 52 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "significantly reduced infectivity" in claims 36 and 52 is a relative term which renders the claim indefinite. The term "significantly reduced" is not defined by the claim, or in

the specification; therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. Claims 56-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 56 recites the limitation "the FIV-141" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 57-60 depend upon claim 56 and are therefore rejected for the same reason.

Claim Rejections - 35 USC § 112, First Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 36-44 and 51-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed."

In the instant case, the claims encompass any and all mutations in the MA, CA, NC, ENV,SU, V3/4, V7/8, TMf, CT, DU, IN, Vifn, Vifc, Vif, ORF2 and RRE genes in any and all lentiviruses. However, the specification only describes specific deletions in FIV-141 genes (see Table 1) and only certain specific double-gene deletions of FIV-141 genes (described on page 31, line 22 – page 32, line 17). Therefore, any mutations not described in the specification lack written description. Specifically, the only claimed embodiments which are adequately described are: FIV-141 lentivirus comprising the specific mutations described in Table 1 (p. 11-12), and on p. 31, line 22 through p.32, line17). All other embodiments, including any lentivirus other than FIV-141 and mutations other than the specifically described deletions lack written description.

The function of the mutated genes is to confer a phenotype unto the lentivirus wherein the lentivirus replicates in host cells, but has significantly reduced infectivity relative to the wild-type lentivirus. However, there is no disclosure in the specification that any mutations other than those specifically described in Table 1 and on p. 32-33, would confer such a phenotype to any lentivirus other that FIV-141.

While the specification provides adequate description for the claimed invention only with regards to FIV-141 virus comprising the specification-disclosed single gene deletions (MA, CA, NC, ENV, SU, V3/4, V7/8, TMf, CT, DU, IN, Vifn, Vifc, Vif , ORF2 and RRE –see Table 1, p. 11-12) and provides adequate description for mutation in two genes wherein the mutations are deletions only in the gene pairs MA/TMf, MA/V3-4, MA/Vif or ENV/IN (as disclosed on page 31, line 22 – page 32, line 17), the specifications fails to describe the other species of mutated lentiviruses encompassed by the claims with particularity to indicate that applicants had possession of the claimed invention. The claimed invention as a whole is not adequately

described if the claims require essential or critical elements which are absent from the specification and which are not conventional in the art as of the applicants' effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as they relate to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

It was unknown as of the applicants filing date whether other embodiments of the invention would have the same properties (i.e. function) as those specifically described in Table 1 and on page 31-32. The skilled artisan cannot envision the detailed chemical structure of all of the encompassed mutations and combinations thereof. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential means of isolating or creating it.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the application at the time of filing, there is no record or description which would demonstrate conception of any lentivirus comprising any gene mutation other than those expressly disclosed. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claims 56-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 56 references specific, deposited virus (FIV-141); however, the deposit rules are not met. MPEP 2402 states "Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112." Specifically, the specification fails to provide the correct (new) address of the depository, a taxonomic description of the deposit, a statement that all restrictions will be lifted on accessing the deposit upon patent issuance, and there is no statement regarding the term of the deposit. Proper amendment is required. Claims 57-60 depend upon claim 56 and are therefore rejected for the same reason.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 36-43, 51, 52, 54, 55 and 61 rejected under 35 U.S.C. 102(b) as being anticipated by Looney et al. (WO 94/17825, 1994).

Looney teaches methods of making an attenuated lentivirus that replicates in host cells but that has significantly reduced infectivity relative to its wild-type counterpart, or a nucleic acid molecule encoding said lentivirus, comprising mutating one or more genes of the lentivirus selected from the group consisting of MA, CA, NC, DU, ENV, SU, TMf, CT, V3/4, V7/8, Vif, Vifn, Vifc, IN, RRE, and ORF(2) (here, Looney teaches an attenuated HIV virus deleting portions of at least three of following genes: env, nef, rev, vif; e.g., see p. 2, line 25 through p. 4, line 14).

Looney also teaches that in addition to the env, nef, rev, and vif deletions, a deletion is made in int (integrase, referred to as "IN" in the application) (see p. 3, lines 21-34; and p. 4, lines 1-14).

Looney teaches a method of producing a nucleic acid molecule comprising:

a) reverse transcribing said lentivirus's genomic DNA;

b) cloning the reverse transcript of step (a);

c) mutating one or more genes in the cloned nucleic acid step (b), wherein said genes are selected from the group consisting of MA, CA, NC, DU, ENV, SU, TMf, CT, V3/4, V7/8, Vif, Vifn, Vifc, IN, RRE, and ORF(2); and

d) cloning the mutated nucleic acid of step (c).

Here, Looney teaches using the methods of Fisher et al. (Nature 316:262-265; 1985), Lee et al. (AIDS Res. And Hum. Retrovir., 5:441-449; 1989) and Ivanoff et al. (AIDS Res. And Hum. Retrovir., 7:595-603; 1989) to make mutations in env, nef, rev, and vif genes of a nucleic acid

cloned from lentivirus DNA, which produces an attenuated virus (see p. 3, lines 1-20; the Fisher, Lee, and Ivanoff references indicate the precise steps for cloning and mutation of cloned genes).

Looney also teaches a host cell transfected with a nucleic acid prepared by claim 51 (see Figure 3, and description on pp. 5, line 35- p. 6, line 8).

13. Claims 36-41, 44, 51, 52, 54, 55 and 61 are rejected under 35 U.S.C. 102(a) as being anticipated by Luciw et al. (WO 97/32983 published Sept 12, 1997).

Luciw teaches methods of making an attenuated lentivirus that replicates in host cells but that has significantly reduced infectivity relative to its wild-type counterpart, or a nucleic acid molecule encoding said lentivirus, comprising mutating one or more genes of the lentivirus selected from the group consisting of MA, CA, NC, DU, ENV, SU, TMf, CT, V3/4, V7/8, Vif, Vifn, Vifc, IN, RRE, and ORF(2) (here, Luciw teaches an live-attenuated FIV comprising deletions of vif, OrfA/2, env, pol, gag, rev and LTR elements; see. P. 10, line 7-23. Luciw defines "attenuated" as, "reduced pathogenesis, e.g. reduced replication capacity or viral load of the attenuated FIV as compared to the wild type biological FIV" see p. 9, line 14-17).

Luciw also teaches that one or more of the genes are modified, and two or three mutated genes are preferred (see p.13, lines3-5 and 27-38).

Luciw teaches a method of producing a nucleic acid molecule comprising:

a) reverse transcribing said lentivirus's genomic DNA;

b) cloning the reverse transcript of step (a);

c) mutating one or more genes in the cloned nucleic acid step (b), wherein said genes are selected from the group consisting of MA, CA, NC, DU, ENV, SU, TMf, CT, V3/4, V7/8, Vif, Vifn, Vifc, IN, RRE, and ORF(2); and

d) cloning the mutated nucleic acid of step (c).

(here, Luciw teaches that the deletions are made in genes of the wild-type molecular clone of FIV-pPPR, see p. 5, lines 36-38; and precisely details the construction of the mutants and attenuated virus on p. 21, lines 9-31).

Luciw also teaches a host cell transfected with a nucleic acid prepared by claim 51 that produces an attenuated FIV that replicates in feline cells, but is attenuated compared to wild-type FIV (see p. 22, lines 1-21 and Figure 3).

Miscellaneous

It is noted that the prior art is believed to be free of any reference to FIV-141. Therefore, amending the claims rejected under 35 U.S.C. 102 to recite FIV-141 would obviate the prior art rejections. However, the written description issues pertaining to all possible mutations and combination of mutations of FIV-141 genes would still apply. Amending the claims to recite the specific mutations for which adequate written description is provided (see above) would obviate the written description rejections.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
June 17, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER